

Appeal No. 24-1555

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

TRUTEK CORP.,

Plaintiff-Appellant,

v.

BLUEWILLOW BIOLOGICS, INC.,

Defendant-Appellee

**ROBIN ROE 1 THROUGH 10,
ABC CORPORATION 1 THROUGH 10**

Defendants.

On Appeal from the United States District Court
for the Eastern District of Michigan
Hon. F. Kay Behm

District Court Case No. 4:21-cv-10312-FKB

**NONCONFIDENTIAL RESPONSE BRIEF OF
APPELLEE BLUEWILLOW BIOLOGICS, INC.**

FOLEY & LARDNER LLP
Liane Peterson
Bradley Roush
Washington Harbour
3000 K Street, N.W., Suite 600
Washington, DC 20007-5101
Telephone: 202.672.5300
Facsimile: 202.672.5399

*Attorneys for Appellee BlueWillow
Biologics, Inc.*

FORM 9. Certificate of Interest

Form 9 (p. 1)
March 2023

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 24-1555

Short Case Caption Trutek Corp. v. BlueWillow Biologics, Inc.

Filing Party/Entity BlueWillow Biologics, Inc. / Appellee-Defendant

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 03/22/2024

Signature: /s/Liane M. Peterson

Name: Liane M. Peterson

FORM 9. Certificate of Interest

Form 9 (p. 2)
March 2023

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).	3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. <input checked="" type="checkbox"/> None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. <input checked="" type="checkbox"/> None/Not Applicable
BlueWillow Biologics, Inc.		

 Additional pages attached

FORM 9. Certificate of Interest

Form 9 (p. 3)
March 2023

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

None/Not Applicable Additional pages attached

Nicholas J. Ellis	Alan J. Gocha	

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

Yes (file separate notice; see below) No N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None/Not Applicable Additional pages attached

TABLE OF CONTENTS

STATEMENT OF RELATED CASES	1
INTRODUCTION	2
STATEMENT OF ISSUES	4
STATEMENT OF THE CASE.....	5
I. Case Overview.....	5
II. Procedural History	6
A. The District Court Properly Refused to Consider Trutek's Claims Directed to BlueWillow's Developmental Vaccines	6
B. Trutek's History of Discovery Failures.....	6
C. Negotiation of Protective Order and the Parties' Treatment of Confidential Information	8
D. BlueWillow's Motion <i>in Limine</i> Related to Damages	10
E. BlueWillow's Motion for Summary Judgment.....	12
F. Trutek's Motion for Reconsideration.....	15
G. Dismissal of Trutek's Case With Prejudice	16
SUMMARY OF THE ARGUMENT	20
ARGUMENT	24
I. Standard of Review	24
A. Summary Judgment.....	24
B. Case Dismissal.....	26
II. The District Court's Grant of Summary Judgment Should be Affirmed	26
A. The District Court Correctly Found Trutek Did Not Meet its Burden to Prove Compliance with Section 287(a) and Granted Summary Judgment of No Pre-Suit Damages.....	27
1. BlueWillow Satisfied its Burden of Production.....	28
2. Trutek Did Not Satisfy its Burden of Proof that Trutek and Trutek's Licensees Complied with § 287(a).....	33

3.	Summary Judgment of No Pre-Suit Damages was Properly Granted, and Need Not be Reviewed if Summary Judgment of No Damages is Affirmed	37
B.	The District Court Correctly Determined Trutek Could Not Meet its Burden to Prove Damages and Granted Summary Judgment of No Damages	38
1.	Trutek's Arguments on Appeal Were Previously Waived at the District Court.....	39
2.	The District Court Correctly Determined The Summary Judgment Record Supported Zero Damages	44
3.	Trutek Remains Precluded from Proving the Amount of Any Damages at Trial	47
III.	The District Court Did Not Abuse its Discretion in Dismissing Trutek's Complaint With Prejudice	49
IV.	CONCLUSION	54

CONFIDENTIAL MATERIAL OMITTED

The material omitted on pages 13, 16, 29, 31 and 32 pertain to Trutek licensee and licensing information.

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>ABS Global, Inc. v. Cytonome/ST, LLC,</i> 984 F.3d 1017 (Fed. Cir. 2021).....	50
<i>Acceleration Bay LLC v. 2k Sports, Inc.,</i> 15 F.4th 1069 (Fed. Cir. 2021)	38
<i>Alpek Polyester, S.A. de C.V., et al. v. Polymetrix AG,</i> No. 2021-1706, 2021 WL 5974163 (Fed. Cir. Dec. 16, 2021).....	25
<i>Already, LLC v. Nike, Inc.,</i> 568 U.S. 85 (2013).....	49, 50
<i>Anderson v. Liberty Lobby, Inc.,</i> 477 U.S. 242 (1986).....	26
<i>Apple Inc. v. Motorola, Inc.,</i> 757 F.3d 1286 (Fed. Cir. 2014).....	40
<i>Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.,</i> 876 F.3d 1350 (Fed. Cir. 2017).....	27, 28, 32
<i>Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.,</i> 950 F.3d 860 (Fed. Cir. 2020).....	24
<i>Aro Mfg. Co. v. Convertible Top Replacement Co.,</i> 377 U.S. 476 (1964).....	40
<i>Bowling v. Hasbro, Inc.,</i> 403 F.3d 1373 (Fed. Cir. 2005).....	26
<i>Celotex Corp. v. Catrett,</i> 477 U.S. 317 (1986).....	26, 27, 37
<i>Cleveland Branch, N.A.A.C.P. v. City of Parma, OH,</i> 263 F.3d 513 (6th Cir. 2001)	49
<i>Cytodyne Techs., Inc. v. Biogenic Techs., Inc.,</i> 216 F.R.D. 533 (M.D. Fla. 2003).....	45

<i>Dow Chem. Co. v. Mee Indus., Inc.</i> , 341 F.3d 1370 (Fed. Cir. 2003).....	40
<i>Dunlap v. Schofield</i> , 152 U.S. 244 (1894).....	27
<i>eBay Inc. v. MercExchange, LLC</i> , 547 U.S. 388 (2006).....	50
<i>Eli Lilly & Co. v. Medtronic, Inc.</i> , 915 F.2d 670 (Fed. Cir. 1990).....	50
<i>Ferring B.V. v. Watson Labs., Inc.-Fla.</i> , 764 F.3d 1382 (Fed. Cir. 2014).....	53
<i>Flagstaff Med. Ctr., Inc. v. Sullivan</i> , 962 F.2d 879 (9th Cir. 1992)	38
<i>Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.</i> , 528 U.S. 167 (2000).....	49
<i>Gen. Elec. Co. v. Joiner</i> , 522 U.S. 136 (1997).....	26
<i>Georgia-Pacific Corp. v. United States Plywood Corp.</i> , 318 F. Supp. 1116 (S.D.N.Y. 1970)	40
<i>Gould v. Control Laser Corp.</i> , 705 F.2d 1340 (Fed. Cir. 1983).....	25
<i>Grain Processing Corp. v. Am. Maize-Prods. Co.</i> , 185 F.3d 1341 (Fed. Cir. 1999).....	40
<i>Gustafson, Inc. v. Intersystems Indus. Prods., Inc.</i> , 897 F.2d 508 (Fed. Cir. 1990).....	39
<i>H.R. Tech., Inc. v. Astechnologies, Inc.</i> , 275 F.3d 1378 (Fed. Cir. 2002).....	53
<i>Horton v. Potter</i> , 369 F.3d 906 (6th Cir. 2004)	26

<i>In re Greektown Holdings, LLC,</i> 728 F.3d 567 (6th Cir. 2013)	25
<i>Info-Hold, Inc. v. Muzak LLC,</i> 783 F.3d 1365 (Fed. Cir. 2015).....	passim
<i>L & W, Inc. v. Shertech, Inc.,</i> 471 F.3d 1311 (Fed. Cir. 2006).....	33, 36, 44
<i>Laitram Corp. v. Cambridge Wire Cloth Co.,</i> 919 F.2d 1579 (Fed. Cir. 1990).....	33, 36, 44
<i>Link v. Wabash R.R., Co.,</i> 370 U.S. 626 (1962).....	26
<i>Loyd v. Saint Joseph Mercy Oakland,</i> 766 F.3d 580 (6th Cir. 2014)	24
<i>Mannington Mills, Inc. v. Armstrong World Indus., Inc.,</i> 206 F.R.D. 525 (D. Del. 2002)	45
<i>Maxwell v. J. Baker, Inc.,</i> 86 F.3d 1098 (Fed. Cir. 1996).....	27, 28, 33, 36
<i>Microsoft Corp. v. DataTern, Inc.,</i> 755 F.3d 899 (Fed. Cir. 2014).....	50
<i>MLC Intell. Prop., LLC v. Micron Tech., Inc.,</i> 10 F.4th 1358 (Fed. Cir. 2021)	25
<i>Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH,</i> 139 F.3d 877 (Fed. Cir. 1998).....	33, 36, 44
<i>Murphy v. Hunt,</i> 455 U.S. 478 (1982).....	49
<i>Nasatka v. Delta Sci. Corp.,</i> 58 F.3d 1578 (Fed. Cir. 1995).....	38
<i>Nat'l Rifle Assoc. of Am. v. Magaw,</i> 132 F.3d 272 (6th Cir. 1997)	49

<i>Rembrandt Vision Techs., L.P. v. Johnson & Johnson Vision Care, Inc.</i> , 725 F.3d 1377 (Fed. Cir. 2013).....	32
<i>ResQNet.com, Inc. v. Lansa, Inc.</i> , 594 F.3d 860 (Fed. Cir. 2010).....	39, 40
<i>Riles v. Shell Exploration & Prod. Co.</i> , 298 F.3d 1302 (Fed. Cir. 2002).....	39
<i>Semiconductor Energy Lab., Co. v. Nagata</i> , 706 F.3d 1365 (Fed. Cir. 2013).....	35
<i>SmithKline Diagnostics, Inc. v. Helena Labs. Corp.</i> , 926 F.2d 1161 (Fed. Cir. 1991).....	38
<i>Spectralytics, Inc. v. Cordis Corp.</i> , 649 F.3d 1336 (Fed. Cir. 2011).....	43
<i>TecSec, Inc. v. Adobe Inc.</i> , 978 F.3d 1278 (Fed. Cir. 2020).....	39
<i>Tolton v. Am. Biodyne, Inc.</i> , 48 F.3d 937 (6th Cir. 1995)	27
<i>United States v. Serta Assoc., Inc.</i> , 29 F.R.D. 136 (N.D. Ill. 1961).....	45
<i>Univ. of W. Va. Bd. of Tr. v. VanVoorhies</i> , 278 F.3d 1288 (Fed. Cir. 2002).....	25
<i>Whitserve, LLC v. Computer Packages, Inc.</i> , 694 F.3d 10 (Fed. Cir. 2012).....	25, 39
<i>Yuba Nat. Res., Inc. v. United States</i> , 904 F.2d 1577 (Fed. Cir. 1990).....	25
Statutes	
35 U.S.C. § 271(e)(1).....	6, 51, 52
35 U.S.C. § 284.....	39, 40
35 U.S.C. § 287(a)	passim

U.S. Const. art. III, § 2	49
Rules	
Fed. R. App. P. 10(a)	47
Fed. R. Civ. P. 37(c)(1).....	passim
Fed. R. Civ. P. 56(a).....	26
Fed. R. Civ. P. 56(c)(1)(A)	42
Other Authorities	
<i>E.D. Mich.</i> LR 5.3(b)(2).....	47
<i>E.D. Mich.</i> LR 7.1(h)(2)(A)	30

STATEMENT OF RELATED CASES

No other appeal involving this case has been before this Court or any other appellate court. BlueWillow Biologics, Inc.'s ("BlueWillow") counsel are not aware of any other case that may directly affect or be directly affected by the Court's decision in this appeal.

INTRODUCTION

Trutek Corp. (“Trutek”) appeals the district court’s grant of summary judgment of no damages and no pre-suit damages, as well as the court’s dismissal of its case without prejudice, arguing that the decision is unfair and unjust. Trutek’s arguments on appeal do not justify reversal, particularly where Trutek has only its own discovery failures to blame. The district court properly granted BlueWillow’s motion *in limine* and excluded all of Trutek’s undisclosed damages-related theories and evidence under Fed. R. Civ. P. 37(c)(1) for failure to disclose pursuant to its discovery obligations. The scope of the order extends to both Trutek’s undisclosed damages theories and undisclosed evidence, including the commissions-based reasonable royalty theory it raises on appeal. Notably, Trutek does not appear to directly appeal this decision. Doc. 15, Trutek Corrected Opening Brief (“CO Br.”) at 2-3 (Introduction) and 5 (Statement of the Issues).

Trutek’s failure to disclose continued through fact discovery, expert discovery and summary judgment. Upon considering the scope of the exclusion order and the available record, the district court properly granted BlueWillow’s motion for summary judgment of no damages and no pre-suit damages. After summary judgment, Trutek raised two new arguments for the first time: (1) the previously undisclosed commissions-based reasonable royalty theory; and (2) Matrixx Initiatives, Inc. (“Matrixx”) is not a licensee of asserted U.S. Patent No.

8,163,802 (“the ’802 patent”). The district court did not ignore Trutek’s new arguments, giving them full consideration on both procedural grounds and on the merits (based on the limited record), before properly dismissing them. These two new arguments form the basis for Trutek’s appeal to this Court.

In view of the summary judgment decision, the district court requested additional briefing on whether there were any remaining issues to litigate, including injunctive relief. After considering the arguments, the district court properly exercised its discretion in dismissing Trutek’s case with prejudice.

Trutek’s appeal, including its motion to supplement the appellate record (Doc. 13) with evidence it repeatedly failed to place into the district court record, merely asks this Court to reconsider the same arguments that were already fully considered and rejected by the district court. The judgment for BlueWillow should be affirmed.

STATEMENT OF ISSUES

1. Whether the district court properly granted BlueWillow summary judgment of no pre-suit damages after finding there was no genuine dispute of material fact that the record evidence did not demonstrate that Trutek or its licensees complied with the marking requirement of 35 U.S.C. § 287(a)?
2. The district court excluded Trutek's lost profits and reasonable royalty damages-related theories and undisclosed evidence under Fed. R. Civ. P. 37(c)(1), a decision that "Trutek does not dispute." In view of that decision, did the district court properly grant BlueWillow summary judgment of no damages upon finding Trutek could not meet its burden of proving the amount of damages?
3. Whether the district court abused its discretion in dismissing the case with prejudice after determining that Trutek's request for an injunction was moot?

STATEMENT OF THE CASE

I. CASE OVERVIEW

BlueWillow is a clinical-stage biopharmaceutical company focused on developing intranasal vaccines for various medical conditions. Appx0519.¹ BlueWillow also developed and sold NanoBio® Protect, an over-the-counter nasal antiseptic that delivers benzalkonium chloride, a common skin antiseptic that has been used for more than 75 years. *Id.*

In its complaint filed on February 10, 2021, Trutek asserted one count of infringement of U.S. Patent No. 8,163,802 against a single product, NanoBio® Protect. Appx0116. Trutek requested five forms of relief in its prayer for relief:

1. Defendants be required to pay over and account to Plaintiff for all gains, profits, and advantages derived from the infringement of its '802 Patent beginning April 24, 2012, based upon manufacture, sales, and/or use of the NANOBIO products in the United States and anywhere in the world, or by way of international commerce with the United States.
2. Defendants be enjoined from manufacturing and/or selling the NANOBIO products in the United States, either directly or indirectly.
3. Defendants be enjoined from actively inducing others to sell the NANOBIO products in the United States, either directly or indirectly.
4. Defendants be enjoined from exporting the NANOBIO products from the United States, either directly or indirectly.
5. Plaintiff prays for such other and further relief as the Court may deem to be just and proper.

Appx0116-17.

¹ The redacted version of BlueWillow's summary judgment motion filed with the district court is included in the public appendix and the unredacted version filed under seal in the district court is included in the confidential appendix.

II. PROCEDURAL HISTORY

A. The District Court Properly Refused to Consider Trutek's Claims Directed to BlueWillow's Developmental Vaccines

On May 11, 2022, Trutek filed a motion for leave to amend the complaint to add infringement allegations directed to BlueWillow's developmental vaccines. On June 6, 2022, the district court denied Trutek's motion based on futility, finding the developmental vaccines "are protected under the safe harbor provision of 35 U.S.C. § 271(e)(1)." Appx0426; Appx0428.

The district court revisited the developmental vaccines when addressing Trutek's argument that its request for injunctive relief "remains a viable remedy that would redress Trutek's injury threatened by future infringement." Appx0091. The district court rejected Trutek's argument on several grounds, noting that Trutek's argument was directed to "different injuries" for "unpled claims" and that any "injunction would have to specifically exclude BlueWillow's vaccine activities" as they remain protected by the safe harbor. Appx0091; Appx0094-95.

B. Trutek's History of Discovery Failures

Per the original scheduling order, discovery was to conclude by April 1, 2022. Appx0442. In anticipation of that deadline, BlueWillow served its First Set of Interrogatories and First Set of Requests for Production on February 18, 2022. *Id.* On March 18, 2022, two days before its responses to BlueWillow's first discovery requests were due, Trutek moved to modify the scheduling order to

extend discovery by 45 days. *Id.*; Appx0009. Close of fact discovery was extended to May 16, 2022, opening expert reports were extended to June 27, 2022, and expert discovery was extended through November 14, 2022. Appx0009.

Trutek belatedly responded to BlueWillow's First Set of Interrogatories on May 11, 2022, missing the original 30-day deadline and the extended 75-day deadline. Appx0443; Appx0010.

BlueWillow's Interrogatory No. 10 asked Trutek to identify the specific categories of damages claimed, the amount for each category and how it was calculated, along with all documents, evidence and persons knowledgeable about such contentions. Appx0011. Trutek responded by stating it sought lost profits and would present the calculation through a damages expert. Appx0011-12. The district court concluded that “[b]y exclusion, Trutek notified BlueWillow that it does not seek a reasonable royalty.” Appx0016.

BlueWillow's Interrogatory No. 9 requested Trutek to identify each person it anticipated would testify at trial including a summary of each person's anticipated testimony. Appx0443. Trutek identified “[a]t least one additional expert to testify regarding damages.” Appx0444. BlueWillow's Interrogatory No. 8 asked Trutek to disclose the licensing terms from comparable licenses with third parties. Appx0013. Trutek responded that the information was confidential and would be produced upon entry of a protective order. Appx0013-14.

BlueWillow's Interrogatory Nos. 12 and 13 requested Trutek to disclose information regarding the timeframes during which Trutek's products, and the products of its licensees, were marked with the '802 patent. Appx0056. Trutek again stated the information was confidential and would be produced upon entry of a protective order. *Id.*

During expert discovery, both parties exchanged expert reports on infringement and validity. Despite telling BlueWillow it would present its "lost profits calculation through a damages expert, Trutek did not identify a damages expert or serve an expert report on damages." Appx0016-17. Trutek ultimately did not produce any damages evidence or disclose any of its damages theories and "never corrected or supplemented its discovery responses." Appx0015.

C. Negotiation of Protective Order and the Parties' Treatment of Confidential Information

When discovery commenced, the parties had not yet agreed upon a protective order. Accordingly, BlueWillow withheld highly confidential financial information from its discovery responses pending entry of that protective order. Appx0010-11; *but see* CO Br. at 7. On June 1, 2022, BlueWillow's counsel provided a revised protective order to Trutek's counsel that it understood addressed all outstanding issues. Appx0503-04. On June 4, 2022, Trutek's counsel confirmed receipt of the draft and stated it was planning to finalize for execution the

following week. Appx0502. Trutek never provided the updated draft and did not file the protective order with the court. Appx0027-29; *but see* CO Br. at 8.

On June 4, 2022, BlueWillow nonetheless provided Trutek with a confidential document containing sales information for NanoBio® Protect (the “sales document”) in anticipation of the “fast approaching June 14, 2022 mediation.” Appx0014. BlueWillow disagrees that “[t]he data necessary to compute a reasonable royalty is contained in the ‘sales document.’” CO Br. at 10. On summary judgment, Trutek did not rely on each of the categories of purported “data” on summary judgment that it identifies on appeal (CO Br. at 10), the document was never submitted to the district court so its contents cannot be verified, and the purported “fact testimony” was never disclosed or part of the summary judgment record. Appx0022; Appx0030; Appx0043; Appx0047.

While BlueWillow produced the sales document shortly after fact discovery closed, the district court concluded that “BlueWillow did not delay the production of the sales document.”² Appx0026; Appx0028. The district court explained that “the parties effectively stipulated to conducting discovery on a confidential basis through their attorneys pending the entry of a protective order” and that while

² Trutek’s assertion that BlueWillow produced the document “[a]pproximately two months after the close of fact discovery” (CO Br. at 51) is false. BlueWillow produced the document approximately two weeks after the May 16, 2022 close of fact discovery.

“BlueWillow cooperated on a mutually agreeable protective order,” Trutek’s explanation for why it failed to disclose its damages-related theories or evidence based on the lack of a protective order and any alleged delay in production of the sales document was “unfounded” and “unreasonable.” Appx0028-30.

D. BlueWillow’s Motion *in Limine* Related to Damages

On September 26, 2022, BlueWillow timely filed a motion *in limine* to exclude Trutek’s damages-related theories or evidence under Fed. R. Civ. P. 37(c)(1). Appx0430-78; *see also* Appx0031. The district court granted “the requested exclusion of Trutek’s damages-related theories or evidence,” noting that “in the six months after BlueWillow filed its motion *in limine*, Trutek has not even belatedly disclosed its damages theories.” Appx0018; Appx0021; Appx0034.

With respect to a reasonable royalty,³ the district court found that “[a]mong other basic elements of its claim for damages, Trutek has not disclosed . . . a claimed royalty rate to be applied to BlueWillow’s sales.” Appx0022. Further, “[a]fter identifying ‘an expert yet to be engaged’ as its only damages witness, Trutek makes passing references to ‘fact testimony’ from ‘Trutek personnel’ without identifying the Trutek witnesses or the subjects of their purported testimony.” *Id.* Stating that the claimed royalty rate was independent of

³ Because Trutek has conceded that it no longer seeks lost profits (CO Br. at 3, 56), BlueWillow does not address the portions of the briefing and orders that pertain solely to lost profits.

BlueWillow's sales data and implicated "damages evidence solely in Trutek's possession," the district court found "[a]s with the Trutek witnesses and the subjects of their purported testimony, it was unreasonable for Trutek to not disclose these basic elements of its claim for damages and supporting damages evidence in its own possession." Appx0030. The district court further explained that "[a]s opposed to a late disclosure, the issue here is the *non-disclosure* of Trutek's damages-related theories or evidence." Appx0034 (emphasis in original).

The district court's order "precludes Trutek from relying on undisclosed damages evidence, including unidentified testimony from unidentified damages witnesses, in support of undisclosed damages theories." Appx0035. The court clarified that the only exception to the order was that the "exclusion does not apply to the sales document and its financial data for sales of the accused NanoBio product." Appx0035. As to the specific categories of "non-disclosure" that are covered by the exclusion order, the district court explained:

- "Trutek has not even belatedly disclosed its damages theories or its damages evidence";
- "As to the floor for a damages award, although Section 284 of the Patent Act entitles Trutek to a reasonable royalty, Trutek notified BlueWillow that it does not seek a reasonable royalty. And in any event, as with lost profits, Trutek has not disclosed either a claimed

royalty rate to be applied to BlueWillow's sales or supporting damages evidence in its own possession."

Appx0035-36. The district court justified its decision noting that "[a]lthough the court's exclusion effectively precludes Trutek from seeking damages, this is only because that which Trutek seeks to present and that which Trutek has not disclosed pursuant to its discovery obligations are one and the same." Appx0036.

E. BlueWillow's Motion for Summary Judgment

On March 28, 2023, BlueWillow filed a motion for summary judgment of non-infringement, invalidity, and no remedy. Appx0518-19. With respect to remedy, BlueWillow separately moved on three issues: (1) no damages; (2) no pre-suit damages for failure to mark; and (3) no injunctive relief. *Id.* The district court granted summary judgment of no damages and no pre-suit damages, but requested additional briefing on injunctive relief, noting that Trutek did not respond to BlueWillow's arguments on the issue. Appx0040; Appx0052; Appx0058-59.

With respect to the issue of no damages, the district court addressed BlueWillow's sales document as "the only piece of damages evidence produced by either party," while noting that it "is not of record." Appx0043. Instead of filing the confidential document under seal, Trutek merely represented to the district court in its responsive brief that the sales document "demonstrates the number of sales, the amount of sales, and the customers to whom the sales were made." Appx0047.

The district court expressly considered Section 284, noting that “district courts must consider the *Georgia-Pacific* factors and award whatever reasonable royalty the record will support.” Appx0049. The district court explained that “[w]hile this case does not involve a complete lack of damages evidence, a hypothetical negotiation would inevitably be speculative” because “the sales document only goes to the damages base of BlueWillow’s sales, not a royalty rate to be applied to BlueWillow’s sales.” Appx0050. As to the royalty rate, the district court found that “speculation and conjecture would be the only factors in a reasonable royalty calculation” and accordingly, “Trutek cannot meet its burden of proving the amount of a reasonable royalty.” *Id.*

With respect to the issue of pre-suit damages and BlueWillow’s burden of production to identify unmarked articles, the district court relied on a declaration submitted by BlueWillow’s counsel. Appx0559-63⁴ (“the Peterson declaration”). The Peterson declaration explained that two products manufactured by Matrixx were not marked with the ’802 patent. Appx0562 at ¶ 11. It also explained BlueWillow’s belief that Matrixx was a licensee to the ’802 patent, attaching as an exhibit a document produced by Trutek entitled [licensee information] that

⁴ The redacted version of the declaration filed with the district court is included in the public appendix and the unredacted version filed under seal in the district court is included in the confidential appendix.

included Matrixx. *Id.* at ¶¶ 10-11; Appx0872.⁵ The Peterson declaration further explained BlueWillow’s belief that the Matrixx products practiced the ’802 patent because Trutek had previously filed a lawsuit against Matrixx, alleging the same products infringed the ’802 patent. *Id.* Trutek did not respond to this argument in its response to BlueWillow’s summary judgment motion. Appx0952-70; Appx0069 (“On summary judgment, Trutek never rebutted the Peterson Declaration or raised the issue of whether BlueWillow has met its initial burden of production. Likewise, Trutek submitted the Kremen Declaration and argues that Matrixx is not a Trutek licensee for the first time in requesting reconsideration.”).

The district court considered the only marking evidence of record, expert testimony from two Trutek technical experts, finding it “does not demonstrate that Trutek and Trutek licensees consistently marked substantially all patented products with the ’802 Patent number or create a genuine dispute on this point.” Appx0054; Appx0057. The district court also addressed Trutek’s attorney argument that “it has marked ‘every’ patented NasalGuard product with the ’802 Patent number since 2013,” noting that Trutek provided no factual support for the statement other than to point out that it could be shown through testimony from Trutek witnesses. Appx0055-56. The district court explained that the same Fed. R. Civ. P. 37(c)(1)

⁵ The redacted version of the exhibit filed with the district court is included in the public appendix and the unredacted version filed under seal in the district court is included in the confidential appendix.

exclusion analysis applies to Trutek’s undisclosed marking evidence, finding it “unreasonable for Trutek to not disclose the requested marking information and supporting marking evidence in its own possession.” Appx0056-57. The district court determined that “the purported testimony from Trutek witnesses does not preclude summary judgment” because the “testimony is neither evidence nor of record.” Appx0057. The district court concluded that the “only marking evidence of record, the expert testimony, does not demonstrate that Trutek and Trutek licensees consistently marked substantially all patented products with the ’802 Patent number or create a genuine dispute on this point.” *Id.*

F. Trutek’s Motion for Reconsideration

After the district court granted in part⁶ BlueWillow’s motion for summary judgment of no remedy, (Appx0052; Appx0058), Trutek moved for reconsideration of the portion of the order granting summary judgment of no pre-suit damages, arguing that the court erred in finding BlueWillow met its initial burden of production (Appx0998-1015). Specifically, Trutek argued the Peterson declaration was “based on the ‘erroneous assumption’ that Matrixx is a Trutek licensee,” relying on a declaration of counsel in support (“the First Kremen declaration”). Appx0066-67. Trutek did not, however, “disaffirm its previous

⁶ The district court’s grant of summary judgment on remedy issues was partial because it requested additional briefing on injunctive relief.

allegation that Matrixx's products are covered by the '802 Patent." Appx0067; *see* Appx1010-11; *but see* CO Br. at 14 ("The ZICAM® products, sold by Matrixx, do not employ the technology of the '802 Patent."). Nor did Trutek enter the actual Trutek-Matrixx agreement into the record, or address the document it produced identifying [redacted] licensee information [redacted]. Appx0998-1015; Appx0070.

The court denied Trutek's motion for reconsideration, finding "Trutek ha[d] not met any of the three requirements for reconsideration." Appx0069. In reaching that decision, the court concluded "Trutek's argument and supporting evidence are new" and untimely because "[o]n summary judgment, Trutek never rebutted the Peterson Declaration or raised the issue of whether BlueWillow has met its initial burden of production." Appx0069-70; Appx0075-76. Further, Trutek's argument was "legally unsupported and inevitably fails on the merits." Appx0070. The district court also determined that Trutek failed to show that correcting the purported "mistake" would change the outcome of the summary judgment order because "the outcome of no pre-suit damages is already subsumed by the outcome of no damages." Appx0073.

G. Dismissal of Trutek's Case With Prejudice

Following summary judgment, the district court requested additional briefing on whether Trutek's remaining request for injunctive relief was moot. Appx0079.

Earlier on summary judgment, BlueWillow explained it was undisputed that the only accused product, NanoBio® Protect, was no longer being sold and that “the warning letter issued by the FDA to BlueWillow concerning the prior sale of NanoBio® Protect renders it unlikely that the product will ever be re-introduced into the U.S. market.” Appx0548. In its opening brief on mootness, BlueWillow reaffirmed that it had no intention to resume sales of the accused NanoBio® Protect. Appx1033. BlueWillow requested the district court dismiss the case with prejudice, noting Trutek should not be permitted to refile to fix the numerous discovery deficiencies that led to the motion in *limine* and motion for summary judgment decisions. Appx1031 at n.1.

In response, Trutek sought to reopen its damages case by presenting a previously undisclosed commissions-based reasonable royalty theory. Appx0088. With respect to injunctive relief, Trutek argued it was insufficient that BlueWillow offered to stipulate to not sell NanoBio® Protect because the stipulation should also cover BlueWillow’s developmental vaccine products to protect against acts of future infringement. Appx1053.

Along with its reply, BlueWillow filed a sworn declaration from its President and Chief Executive Officer, Chad Costley, stating “BlueWillow will not sell NanoBio® Protect at any time in the future.” Appx1080; Appx1083 at ¶ 8. The declaration further stated BlueWillow was at least 5 years from commercializing

its developmental vaccines and the nanoemulsion adjuvant in the vaccines “is not the same formulation in NanoBio® Protect in that it includes different ingredients and different concentrations of ingredients.” Appx1082-83 at ¶¶ 6-7.

On February 2, 2024, the district court dismissed Trutek’s complaint with prejudice. Appx0080; Appx0101. Considering the voluntary cessation doctrine, the district court determined that BlueWillow “met its burden of showing that ‘the allegedly wrongful behavior,’ infringement by the accused NanoBio® product, ‘could not reasonably be expected to recur.’” Appx0090. The district court considered BlueWillow’s sworn declaration to be functionally equivalent to a covenant “that BlueWillow will not make, use, sell, offer to sell, or import the accused NanoBio® product until after the ’802 Patent expires.” *Id.* The district court noted that the covenant was “coextensive” with Trutek’s infringement claim and requested injunctive relief (Appx0116-17), and as such, gave “Trutek exactly what it requested in the complaint.” Appx0090-91. The district court explained that Trutek’s demand for the covenant to cover the developmental vaccines was “unreasonable” because the parties had not litigated the issue of whether the vaccines infringe or conducted any discovery on the vaccines, and because the vaccines are protected under the safe harbor. Appx0093-35 (relying on Federal Circuit precedent that “injunctive relief must be predicated on a judgment of

infringement, and that the scope of judgment cannot extend beyond the issues that were actually litigated and adjudicated”).

The district court also addressed Trutek’s new commissions-based reasonable royalty theory, declining to consider the argument on multiple grounds: (1) unauthorized; (2) waived for not being raised earlier on summary judgment; and (3) factually unsupported because the sales document still had not been placed in the record. Appx0088-89.

Finally, with respect to the issue of declaratory relief, the district court found “that declaratory relief as to the infringement and validity issues would be unnecessary and inappropriate in this case.” Appx0097-98 (“Moreover, as to the infringement issue, the court cannot grant declaratory relief that affects BlueWillow’s behavior toward Trutek. The court has held that Trutek cannot recover damages, and BlueWillow already removed the accused NanoBio® product from the market. Accordingly, a favorable judgment to Trutek would amount to nothing more than a declaratory judgment of past infringement. Rather than properly affecting BlueWillow’s behavior, Trutek’s above arguments make clear that its only interest in a favorable judgment is to further its unsubstantiated and premature demands against the unlitigated and safe harbor-protected developmental vaccines.”).

SUMMARY OF THE ARGUMENT

Trutek seeks to overturn three rulings of the district court. CO Br. at 5. Unfortunately for Trutek, the district court ruled against Trutek in all three instances due to Trutek’s repeated failure to satisfy its discovery obligations, support its summary judgment arguments with admissible evidence, and properly follow the district court’s local rules, rendering it impossible for Trutek to satisfy its burden of proof to establish damages or raise a genuine issue of any material fact to avoid summary judgment. While undoubtably Trutek may be unhappy with the district court’s decision, it only has its own deficient conduct to blame. Nor did the district court “ignore” any of Trutek’s arguments. In each instance, the district court reached the correct conclusion based on the evidence presented to it by the parties and under controlling legal precedent and applicable local rules.

First, the district court granted summary judgment of no pre-suit damages because Trutek failed to “demonstrate that Trutek and Trutek’s licensees consistently marked substantially all patented products with the ’802 Patent number or create a genuine dispute on this point.” Appx0057. Based on discovery provided by Trutek and Trutek’s prior litigation history, BlueWillow presented evidence to the district court demonstrating its belief that a licensee of the ’802 patent failed to mark patented products. Appx0562 at ¶ 11; Appx0872. Having put Trutek on notice of a suspected violation of 35 U.S.C. § 287(a) by one of its

licensees, the burden of proof shifted to Trutek to demonstrate the identified products did not practice the patent. Trutek, however, never responded to BlueWillow's arguments in opposing the motion for summary judgment. Appx0951-53. With respect to its own marking practices, Trutek only pointed to unsubstantiated statements from its experts suggesting that at a single point in time, unspecified Trutek products were marked with the '802 patent. The district court correctly concluded that these facts, even viewed in a light most favorable to Trutek, were insufficient to meet Trutek's burden of proof to establish compliance with 35 U.S.C. § 287(a) and granted summary judgment of no pre-suit damages.

Subsequently, Trutek moved for reconsideration disputing BlueWillow's position that a Trutek licensee failed to mark its licensed products. Appx0998-1020. Trutek's motion attempted to introduce new argument and evidence that was not before the district court when it rendered its decision, and Trutek offered no explanation for why it did not raise the argument earlier. The district court properly concluded that Trutek had waived its new and untimely argument. Because the new argument was not before the court when it rendered its summary judgment decision, it should not be considered by this Court.

Second, the district court granted summary judgment of no damages because Trutek failed to meet its burden of showing the "but for" causation that would

entitle it to lost profits,⁷ Appx0047-48, and failed to meet its burden of proving the amount of a reasonable royalty, Appx0050. In opposing BlueWillow's motion for summary judgment Trutek relied on a single document to support its claim for reasonable royalty damages, *id.* ("[T]he sales document is Trutek's only piece of damages evidence."), but critically, never submitted the sales document to the district court for consideration. Trutek's only excuse for its failure to do so, despite repeated admonishment by the court, was based on the fact that BlueWillow designated the sales document as Attorneys' Eyes Only due to the sensitive nature of the information contained within the document. Despite having access to procedures by which it could file the sales document with the court under seal, Trutek chose instead to generally describe its contents to the district court.⁸ Appx0947-49. While Trutek asserted on summary judgment that certain information in the sales document was sufficient to demonstrate a reasonable royalty, the court properly found that it could not consider Trutek's argument without the document in the record. Appx0047. Further, Trutek also failed to articulate what that reasonable royalty may be or how it could be determined and

⁷ Trutek now admits that it introduced no evidence of lost profits and no longer seeks lost profits as a remedy. CO Br. at 3, 56.

⁸ Trutek was repeatedly criticized by the district court for failing to put this document on the record. Appx0088-89 ("Trutek has not placed the sales document in the record. . . . Notably, the court has admonished Trutek for the same failure on two previous occasions.").

as such, the court properly concluded that “speculation and conjecture would be the only factors in a reasonable royalty calculation.” Appx0050. The district court correctly concluded that these facts, even viewed in a light most favorable to Trutek, were insufficient to meet Trutek’s burden of proving the amount of damages and granted summary judgment of no damages. Appx0051-52.

Third, the district court found Trutek’s remaining request for relief, an injunction, was moot and dismissed the case with prejudice. Appx0099; Appx0101. Shortly after the complaint was filed, BlueWillow withdrew the accused NanoBio® Protect product from the market. Appx0195; Appx0205; Appx0609-14. BlueWillow confirmed that it has no intention of resuming sales and filed a sworn declaration from its President and CEO to that effect. Appx1083 at ¶ 8. The district court properly concluded BlueWillow had met its burden under the voluntary cessation doctrine and exercised its discretion to determine an injunction was not necessary. Appx0090. As there was no remaining claim for relief the district court could award Trutek upon a finding of infringement of a valid patent claim, the district court did not abuse its discretion in dismissing the case with prejudice.

ARGUMENT

I. STANDARD OF REVIEW

A. Summary Judgment⁹

“We review a district court’s grant of summary judgment according to the law of the regional circuit.” *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 950 F.3d 860, 863 (Fed. Cir. 2020). This applies to summary judgment decisions as to both pre-suit damages, *see id.* (applying Eleventh Circuit standard when reviewing summary judgment decision of no pre-suit damages when licensee did not properly mark products), and the availability of damages, *see Info-Hold, Inc. v. Muzak LLC*, 783 F.3d 1365, 1371 (Fed. Cir. 2015) (applying Sixth Circuit standard when reviewing summary judgment decision of no damages for lack of supporting evidence). The Sixth Circuit reviews a district court’s grant of summary judgment de novo. *See id.* (citing *Loyd v. Saint Joseph Mercy Oakland*, 766 F.3d 580, 588 (6th Cir. 2014)).

Although Trutek does not appear to directly appeal the district court’s grant of BlueWillow’s motion *in limine* and the denial of Trutek’s motion for reconsideration, out of abundance of caution, BlueWillow provides the applicable

⁹ Trutek states the standard of review for summary judgment decisions is de novo. CO Br. at 28. BlueWillow agrees with this assessment. However, in its Statement of the Issues, Trutek appears to apply the abuse of discretion standard. *Id.* at 5. In an attempt to clarify the issue, and provide supporting case law, BlueWillow restates the applicable standard of review here.

standards of review for those procedural decisions. ““When reviewing damages in patent cases, [the Federal Circuit] appl[ies] regional circuit law to procedural issues and Federal Circuit law to substantive and procedural issues pertaining to patent law.”” *MLC Intell. Prop., LLC v. Micron Tech., Inc.*, 10 F.4th 1358, 1367 (Fed. Cir. 2021) (quoting *Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 26 (Fed. Cir. 2012)) (applying Ninth Circuit law when evaluating the district court’s decision to impose discovery sanctions). District court decisions relating to discovery issues are reviewed for abuse of discretion. *Alpek Polyester, S.A. de C.V., et al. v. Polymetrix AG*, No. 2021-1706, 2021 WL 5974163, at *7-8 (Fed. Cir. Dec. 16, 2021) (“The district court is owed broad discretion in enforcing the rules of discovery” and “We defer to the broad discretion of the district court to manage its own docket.”); *see also Univ. of W. Va. Bd. of Tr. v. VanVoorhies*, 278 F.3d 1288, 1304 (Fed. Cir. 2002) (“We decline to interfere with a court’s management of the discovery process absent a showing of a clear abuse of discretion or extreme prejudice”); *Gould v. Control Laser Corp.*, 705 F.2d 1340, 1341 (Fed. Cir. 1983) (“[D]istrict courts have broad discretionary powers to control their dockets.”). District court decisions denying motions for reconsideration are reviewed for abuse of discretion. *See In re Greektown Holdings, LLC*, 728 F.3d 567, 573 (6th Cir. 2013); *Yuba Nat. Res., Inc. v. United States*, 904 F.2d 1577, 1583 (Fed. Cir. 1990).

B. Case Dismissal¹⁰

“We review a district court’s dismissal of a case with prejudice for an abuse of discretion.” *Bowling v. Hasbro, Inc.*, 403 F.3d 1373, 1375 (Fed. Cir. 2005) (citing *Link v. Wabash R.R. Co.*, 370 U.S. 626, 633 (1962)). Under the abuse of discretion standard, a court will not overturn the district court’s decision unless it was manifestly erroneous. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141-42 (1997) (citation omitted).

II. THE DISTRICT COURT’S GRANT OF SUMMARY JUDGMENT SHOULD BE AFFIRMED

Summary judgment is appropriate “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); *see also Info-Hold*, 783 F.3d at 1371. No genuine issue of material fact exists if, by viewing the evidence in a light most favorable to the nonmoving party, a reasonable jury could not return a verdict for that party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

“The moving party discharges its burden by ‘showing—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party’s case.’” *Horton v. Potter*, 369 F.3d 906, 909 (6th Cir. 2004) (quoting *Celotex*

¹⁰ Trutek states that the standard of review for case dismissal is de novo, CO Br. at 28, while it applies the abuse of discretion standard in its argument, *id.* at 5. BlueWillow concurs that abuse of discretion is the appropriate standard.

Corp. v. Catrett, 477 U.S. 317, 325 (1986)). “Summary judgment is appropriate if a party, after adequate opportunity for discovery, ‘fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.’” *Tolton v. Am. Biodyne, Inc.*, 48 F.3d 937, 941 (6th Cir. 1995) (quoting *Celotex*, 477 U.S. at 322).

A. The District Court Correctly Found Trutek Did Not Meet its Burden to Prove Compliance with Section 287(a) and Granted Summary Judgment of No Pre-Suit Damages

“The patentee bears the burden of pleading¹¹ and proving he complied with [35 U.S.C.] § 287(a)’s marking requirement.” *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1366 (Fed. Cir. 2017) (citing *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1111 (Fed. Cir. 1996)). “Whether [a patentee’s] articles have been duly marked or not is a matter peculiarly within his own knowledge; and, if they are not duly marked, the statute expressly puts upon him the burden of proving the notice to the infringers before he can charge them in damages.” *Dunlap v. Schofield*, 152 U.S. 244, 248 (1894); *see also Maxwell*, 86 F.3d at 1111. The marking must be applied to substantially all of the patented products and be “substantially consistent and continuous in order for the party to avail itself of the constructive notice provisions of the statute.” *Maxwell*, 86 F.3d at

¹¹ Trutek did not plead compliance with § 287(a) in its complaint. Appx0110-17.

1111-12 (finding evidence 95% of products were marked was sufficient to meet the § 274(a) requirement).

“A patentee’s licensees must also comply with § 287, because the statute extends to ‘persons making or selling any patented article for or under [the patentee].’” *Arctic Cat*, 876 F.3d at 1366 (quoting *Maxwell*, 86 F.3d at 1111; 35 U.S.C. § 287(a)). The accused infringer has the initial burden of production to identify “the products it believes are unmarked ‘patented articles’ subject to § 287.” *Id.* at 1368. “Once the alleged infringer meets its burden of production, however, the patentee bears the burden to prove the products identified do not practice the patented invention.” *Id.* This applies equally to products manufactured by the patentee and products manufactured by a licensee. *See id.* The alleged infringer’s burden is a “low bar,” needing only to “put the patentee on notice that he or his authorized licensees sold specific unmarked products which the alleged infringer believes practice the patent.” *Id.*

1. BlueWillow Satisfied its Burden of Production

The district court correctly determined based on the summary judgment record that BlueWillow satisfied its burden of production to identify products it believed were unmarked articles that practiced the ’802 patent.

Trutek previously sued Matrixx, accusing Matrixx’s Zicam Extreme Congestion Relief Nasal Spray and Zicam Cold Remedy Nasal Swabs products of

infringing the '802 patent. *See* Appx0562 at ¶ 11 (citing Trutek Corp. v. Matrixx Initiatives, Inc., 3-19-cv-17647 (D.N.J.), Dkt. 58-1, PageID 441-445). The case against Matrixx ultimately settled. During discovery, Trutek produced a document entitled [REDACTED] licensee information [REDACTED] Appx0872. This [REDACTED] licensee information [REDACTED] *Id.* Based on the information contained in this document, BlueWillow reasonably concluded Matrixx is a licensee of the '802 patent. BlueWillow had no reason to doubt the truth of this document, particularly in view of the related litigation where Trutek accused Matrix of infringing the '802 patent.¹²

BlueWillow's counsel purchased the two Matrixx products in January 2023, but, upon inspection, neither product was marked with the '802 patent despite being marked with other patent numbers. *Id.* Through the Peterson declaration submitted in support of its summary judgment motion, BlueWillow put Trutek on notice that (1) its authorized licensee, Matrixx, sold specific unmarked products, Zicam Extreme Congestion Relief Nasal Spray and Zicam Cold Remedy Nasal Swabs, (2) that BlueWillow understood practiced the '802 patent. The burden then shifted to Trutek to demonstrate the unmarked Matrixx products did not practice the '802 patent, or that Matrixx was not a licensee. Trutek, however, did neither and in fact, did not even respond to BlueWillow's arguments in its summary

¹² Trutek did not produce the Trutek-Matrixx agreement during litigation or submit the agreement to the district court for consideration. Appx0070.

judgment opposition. Appx0951-53. At the time that the district court rendered its summary judgment decision, the statements in the Peterson declaration were undisputed, supported by Trutek's own documents and prior litigation history, and the district court correctly found the record "does not demonstrate that Trutek and Trutek licensees consistently marked substantially all patented products with the '802 Patent number or create a genuine dispute on this point." Appx0057.

Thereafter, Trutek filed a motion for reconsideration based on a purported "mistake" by the district court, relying on new argument disputing whether Matrixx was a licensee and practiced the '802 patent. Appx0998-1015; Appx1016-20. The district court correctly denied the motion for reconsideration on multiple grounds, concluding Trutek had not satisfied any of the three requirements for reconsideration under E.D. Mich. LR 7.1(h)(2)(A). Appx0068-69. The district court also determined that the new argument presented in Trutek's motion for reconsideration was improper for not being presented earlier and was "legally unsupported and inevitably fails on the merits." Appx0069-70. The district court concluded that "[c]ontrary to Trutek's new and legally unsupported argument, the court had good reason at the time of the Order to find that Matrixx is a Trutek licensee for purposes of the marking requirement." Appx0070.

Now, on appeal, Trutek points to the same new attorney argument submitted with its motion for reconsideration (CO Br. at 33-36; 47-48 (referring to and citing

Appx0998-1015; Appx1016-20)) while leveling personal attacks at BlueWillow’s counsel (CO Br. at 22, 49). Trutek’s arguments remain meritless at the appellate stage. Indeed, Trutek admits “that facts necessary to correct [the district court’s] mistake was [sic] not part of the record before the Court at the time.” CO Br. at 48. Further, because Trutek does not challenge the court’s denial of its motion for reconsideration, CO Br. at 5, it does not challenge the court’s factual finding that “[o]n summary judgment, Trutek never rebutted the Peterson Declaration or raised the issue of whether BlueWillow has met its initial burden of production.”

Appx0069.

Trutek’s accusation that the Peterson declaration was “false” and counsel’s investigation was “at best negligent” is unfounded as well. CO Br. at 22, 49. BlueWillow’s belief that Matrixx was a Trutek licensee was not “based solely on the fact that Trutek sued Matrixx for infringement of the ’802 Patent, and that the lawsuit was dismissed with prejudice.” *Id* at 49. Indeed, BlueWillow did seek discovery directly from Trutek on this issue. In response to those discovery requests, Trutek produced a document that identified licensee information [REDACTED]. Appx0562 at ¶¶ 10-11; Appx0872. Trutek did not address, or even

acknowledge this document at the district court, nor has it done so here on appeal.¹³

Further, it would have been improper to question Trutek's technical experts about Matrixx's licensing practices simply because of their involvement in the prior Matrixx litigation. *Compare CO Br. at 37 with Rembrandt Vision Techs., L.P. v. Johnson & Johnson Vision Care, Inc.*, 725 F.3d 1377, 1381 (Fed. Cir. 2013) ("An expert witness may not testify to subject matter beyond the scope of the witness's expert report."). Neither expert offered any opinion directed to whether Matrixx's products were subject to the marking requirement of § 287(a).

Contrary to Trutek's unsupported assertions, BlueWillow did not need to prove Matrixx practiced the '802 patent, it only needed to believe it practiced the patent. *Compare CO Br. at 32 with Arctic Cat*, 876 F.3d at 1368 ("The alleged infringer's burden is a burden of production, not one of persuasion or proof."). The record, including Trutek's prior litigation history against Matrixx and Trutek's own document production, demonstrates that BlueWillow's belief that the Matrixx products practiced the '802 patent was reasonable.

¹³ By attempting to dispute the Peterson declaration, Trutek creates a no-win situation for itself. Either Trutek produced false information during discovery identifying [redacted] licensee information or it is currently misrepresenting its relationship with Matrixx.

Because all of Trutek's arguments directed to whether BlueWillow met its burden of production were first raised in Trutek's motion for reconsideration, it necessarily follows they were not before the district court when it ruled on BlueWillow's motion for summary judgment. This Court cannot consider evidence that was not before the district court when ruling on summary judgment. *See L & W, Inc. v. Shertech, Inc.*, 471 F.3d 1311, 1315 n.2 (Fed. Cir. 2006) (citing *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 880 (Fed. Cir. 1998); *Laitram Corp. v. Cambridge Wire Cloth Co.*, 919 F.2d 1579, 1581 & n.4 (Fed. Cir. 1990)). The only evidence in the record when the district court rendered its decision on summary judgment was the undisputed Peterson declaration and the district court did not err in determining that BlueWillow satisfied its burden of production based on that record.

2. Trutek Did Not Satisfy its Burden of Proof that Trutek and Trutek's Licensees Complied with § 287(a)

Trutek's only evidence of patent marking comes from the opinions of its technical experts, Dr. Lemmo and Mr. Haidri. Appx0546-47; Appx0054. The statements by the Trutek experts are poorly supported and do not prove "substantially consistent and continuous" marking of the Trutek products. *Maxwell*, 86 F.3d at 1111. Nor did Trutek offer any evidence on summary judgment as to whether any of Trutek's licensees' products were marked. Appx0056. For example, Dr. Lemmo asserted the "patent number of the '802

Patent is clearly marked for every unit sold in the United States” but did not offer any evidence in support of this statement. Appx0546-47; Appx0054. When questioned at deposition, Dr. Lemmo admitted he had only purchased Trutek’s NasalGuard products in 2020 and had no personal knowledge whether the ’802 patent was marked on these products prior to 2020. Appx0547; Appx0670; Appx0054. Mr. Haidri’s report was equally unsupported, alleging “[a]ll products sold in the United States had the ’802 Patent number printed on the packaging.” Appx0547; Appx0054; Appx0701. Mr. Haidri includes photos of various Trutek NasalGuard products, but not a single image showed the patent number on the packaging. Appx0701. In its response to BlueWillow’s motion for summary judgment, Trutek merely repeated the unsupported assertions of its experts and claimed, for the first time, that additional evidence on patent marking would be introduced by a Trutek employee at trial. Appx0952-53. It did not, however, elaborate on what that additional evidence would be or submit that additional evidence to the court. Appx0055-57.

After reviewing the arguments and evidence offered by both parties, the district court concluded that “[t]he only marking evidence of record, the expert testimony, does not demonstrate that Trutek and Trutek licensees consistently marked substantially all patented products with the ’802 Patent number or create a genuine dispute on this point.” Appx0057. The court also found that while

BlueWillow's interrogatories asked Trutek to disclose information about the timeframes when all patented products were marked, Trutek improperly asserted this information was confidential and refused to produce any information until entry of a protective order. Appx0056. Because the patent marking requirement necessarily addresses the issue of public notice and disclosure, the court properly found it was unreasonable for Trutek to refuse to disclose the marking evidence in its own possession. Appx0056-57.

On appeal, Trutek raises a new argument, pointing to a declaration of counsel filed in support of its own motion for summary judgment. CO Br. at 31. Trutek's motion for summary judgment sought a declaration of validity for the '802 patent and included a declaration submitted by its trial counsel, Stanley Kremen ("the second Kremen declaration").¹⁴ Appx0887 at i. Trutek did not cite the declaration in its motion, but Paragraph 9 notes that Exhibit 3 to the motion "is a true copy of a sample of marking of the '802 Patent on Plaintiff, Trutek Corp.'s products." Appx0921 (referring to Appx0924).

Trutek did not refer to the second Kremen declaration or Exhibit 3 to its motion for summary judgment when responding to BlueWillow's motion for

¹⁴ As noted by both BlueWillow and the district court, "a declaratory judgment of patent validity . . . is not a viable cause of action. *Semiconductor Energy Lab., Co. v. Nagata*, 706 F.3d 1365, 1370 (Fed. Cir. 2013). See Appx0097-98; Appx1073.

summary judgment.¹⁵ Trutek's new argument is untimely and waived. "Evidence that was not before the district court at the time of the summary judgment proceeding . . . cannot be invoked to challenge the summary judgment order." *L & W*, 471 F.3d at 1315 n.2 (citing *Monarch Knitting*, 139 F.3d at 880; *Laitram*, 919 F.2d at 1581 & n.4). Even if considered, the photo provided in the second Kremen declaration does not demonstrate substantially consistent and continuous marking as required under controlling case authority. *Maxwell*, 86 F.3d at 1111. The second Kremen declaration contains only one undated photo, only showing that a single product was marked at a single unknown point in time. Appx0924. Compare this with Mr. Haidri's expert report, which includes photos of multiple different products that allegedly practice the '802 patent (albeit without any evidence that the products were marked with the '802 patent). Appx0701. At no point during litigation did Trutek provide evidence of patent marking for substantially all of the Trutek products it asserts practice the patent. Nor did Trutek provide evidence demonstrating the products were marked at all relevant times before the district court complaint was filed. Likewise, Trutek provided no evidence whatsoever as to whether Trutek's licensees marked their products. Appx0056-57. Thus, the district court properly found the "only marking evidence of record, the expert testimony,

¹⁵ Trutek's motion for summary judgment was filed on March 30, 2023. Appx0886. Trutek's response to BlueWillow's motion for summary judgment was filed on June 1, 2023. Appx0925.

does not demonstrate that Trutek and Trutek licensees consistently marked substantially all patented products with the '802 Patent number or create a genuine dispute on this point." Appx0057.

3. Summary Judgment of No Pre-Suit Damages was Properly Granted, and Need Not be Reviewed if Summary Judgment of No Damages is Affirmed

"[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."

Celotex, 477 U.S. at 322. Based on the evidence of record, no reasonable jury could find Trutek marked substantially all of its products consistently and continuously. And based on the evidence of record, no reasonable jury could find Trutek's licensees marked their products. Despite bearing the burden of proof, Trutek failed to timely introduce any evidence in support of its compliance with § 287(a). Thus, the district court properly concluded on the record before it at summary judgment that Trutek failed to meet the requirements of § 287(a) and properly granted summary judgment of no-pre suit damages.

As noted by the district court, "the outcome of no pre-suit damages is already subsumed by the outcome of no damages." Appx0073 ("Denying BlueWillow's motion for summary judgment of no pre-suit damages would

amount to nothing more than a hollow victory for Trutek on a moot issue.”). In other words, if this Court affirms the district court’s grant of summary judgment of no damages, resolution of Trutek’s appeal on the pre-suit damages issue will have no bearing on whether Trutek can even recover damages due to BlueWillow’s alleged infringement. To the extent Trutek argues the summary judgment decision of no pre-suit damages could impact other future litigations (CO Br. at 47), Trutek provides no explanation for its argument. Nor is the argument persuasive or applicable here. *See Acceleration Bay LLC v. 2k Sports, Inc.*, 15 F.4th 1069, 1077 (Fed. Cir. 2021) (addressing mootness and noting “we are not persuaded that an impact on other cases between [the plaintiff] and third parties confers jurisdiction”); *Nasatka v. Delta Sci. Corp.*, 58 F.3d 1578, 1581 (Fed. Cir. 1995) (“In deciding whether this appeal must be dismissed as moot, we examine whether the decision of any disputed issue ‘continues to be justified by a sufficient prospect that the decision will have an impact on the parties.’”) (quoting *Flagstaff Med. Ctr., Inc. v. Sullivan*, 962 F.2d 879, 884 (9th Cir. 1992)).

B. The District Court Correctly Determined Trutek Could Not Meet its Burden to Prove Damages and Granted Summary Judgment of No Damages

“[T]he amount of [plaintiff]’s damages is a finding of fact on which the plaintiff bears the burden of proof by a preponderance of the evidence.” *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1164 (Fed. Cir. 1991).

Courts will not award patent damages without supporting evidence or if any damages award would be based on mere speculation and conjecture. *See WhitServe LLC v. Comput. Packages, Inc.*, 694 F.3d 10, 29-33 (Fed. Cir. 2012); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 868-73 (Fed. Cir. 2010). A damages theory absent evidence should not be entertained, as evidence is necessary “[t]o prevent the hypothetical from lapsing into pure speculation.” *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1311 (Fed. Cir. 2002) (citation omitted). “The statute does not require an award of damages if none are proven that adequately tie a dollar amount to the infringing acts [and] . . . there can be an award of no damages where ‘none were proven.’” *TecSec, Inc. v. Adobe Inc.*, 978 F.3d 1278, 1291 (Fed. Cir. 2020) (citing *Gustafson, Inc. v. Intersystems Indus. Prods., Inc.*, 897 F.2d 508, 509-10 (Fed. Cir. 1990)).

1. Trutek’s Arguments on Appeal Were Previously Waived at the District Court

Trutek’s appeal of the district court’s grant of summary judgment of no damages is predicated on the assertion that it is entitled to a reasonable royalty under 35 U.S.C. § 284, even where there is no evidence in the record to determine what that reasonable royalty should be. Any award of damages, whether based on a lost profits or reasonable royalty theory, must still be supported by record evidence.

Specifically, while 35 U.S.C. § 284 may require the district court to award damages not less than a reasonable royalty, the reasonable royalty must be based on and supported by reliable evidence. *Info-Hold*, 783 F.3d at 1372 (citing *Dow Chem. Co. v. Mee Indus., Inc.*, 341 F.3d 1370, 1381-82 (Fed. Cir. 2003)). “[I]n a case completely lacking any evidence on which to base a damages award, the record may well support a zero royalty award.” *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1328 (Fed. Cir. 2014) (overruled on other grounds). “A comprehensive (but unprioritized and often overlapping) list of relevant factors for a reasonable royalty calculation appears in *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).” *ResQNet.com*, 594 F.3d at 869. The damages inquiry must be focused on compensation for the economic harm caused by the alleged infringement and proof must be tied to the claimed invention’s footprint in the marketplace. *Id.* (citing *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964); *Grain Processing Corp. v. Am. Maize-Products Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999)).

On appeal, Trutek argues that the district court “held in error that no discovery exists from which a jury can determine a reasonable royalty. Such a royalty may be computed from discovery requested by Trutek and submitted by BlueWillow.” CO Br. at 3-4; *see also* CO Br. at 10 (“The data necessary to

compute a reasonable royalty is contained in the ‘sales document,’ which can be verified by fact testimony.”).

As an initial matter, Trutek mischaracterizes the district court’s summary judgment ruling. The court’s ruling was not based on a finding that “no discovery exists.” Rather, the court ruled that the record on summary judgment, which did not include the sales document, did not include any evidence upon which to determine a royalty rate. Appx0050 (“While this case does not involve a complete lack of damages evidence, a hypothetical negotiation would inevitably be speculative” because “the sales document only goes to the damages base of BlueWillow’s sales, not a royalty rate to be applied to BlueWillow’s sales.”).

Entertaining Trutek’s argument on appeal would require this Court to (1) supplement the record with evidence (*i.e.*, the sales document) that Trutek failed to place into the district court record on multiple occasions and (2) assess a new damages theory (*i.e.*, the commissions-based reasonable royalty theory) that the district court expressly refused to consider because it had been waived below.¹⁶

Trutek’s argument that the sales document contains all of the data needed to compute a reasonable royalty has long been waived. Indeed, Trutek never raised

¹⁶ Trutek’s disclosed its commissions-based reasonable royalty theory for the first time after summary judgment. Appx0088. Thus, this damages theory is also precluded under the district court’s motion *in limine* order, which Trutek does not even appear to challenge. CO Br. at 2-3, 5.

the commissions-based reasonable royalty theory until after the court rendered its summary judgment decision. Only later, when considering whether the case should be dismissed, did Trutek argue for the first time that the sales document purportedly contained information on sales commissions upon which a royalty rate could be calculated. The district court was not made aware of this information when deciding the motion for summary judgment (through Trutek's own fault) and the court properly found Trutek had waived the argument (and yet again had failed to enter the sales document into the record):

The court declines to consider Trutek's argument for a commissions-based reasonable royalty theory. In the court's previous summary judgment Order, the court fully resolved and did not order further briefing on the issue of damages. In addition to being unauthorized, Trutek's argument has long been waived. Trutek did not present a commissions-based reasonable royalty theory in either of its oppositions to BlueWillow's motions (ECF Nos. 43 [(Appx0479-91)], 76 [(Appx0925-70)]) or in its own motion for reconsideration (ECF No. 89 [(Appx0998-1015)]). Moreover, Trutek's argument is factually unsupported. The court could not pass on the merits of Trutek's argument because Trutek has not placed the sales document in the record. See Fed. R. Civ. P. 56(c)(1)(A) (requiring a party to support factual assertions by "citing to particular parts of materials in the record"). Notably, the court has admonished Trutek for the same failure on two previous occasions.

Appx0088-89.

Trutek's remaining arguments are unpersuasive as well. For the reasons explained in BlueWillow's Response and Opposition to Trutek's Motion to Supplement the Record (Doc. 16), the *Spectralytics* case does not support Trutek's

argument that a reasonable royalty can be calculated based on the sales document alone. CO Br. at 25, 45; Doc. 16, BlueWillow’s Response to Trutek’s Motion to Supplement (“BW Resp.”), at 13-14; *Spectralytics, Inc. v. Cordis Corp.*, 649 F.3d 1336, 1346 (Fed. Cir. 2011) (abrogated on other grounds). Indeed, even Trutek admits that further fact testimony would be necessary. CO Br. at 10 (“The data necessary to compute a reasonable royalty is contained in the ‘sales document,’ which can be verified by fact testimony.”). Trutek has not identified what “fact testimony” would be needed; regardless, it would be excluded by the district court’s ruling on the motion *in limine*. Further, although Trutek claims that BlueWillow will “not be surprised by Trutek’s use of this method of calculation because it will use only data provided by BlueWillow in discovery,” (CO Br. at 25, 45) this is directly contrary to the rationale underlying the district court’s order excluding Trutek’s undisclosed damages theories. Appx0024 (“BlueWillow cannot cure the surprise without reopening discovery to explore Trutek’s damages theories and formulate alternative damages theories.”).

While Trutek claims the result is “unjust and unfair” and a “miscarriage of justice” (CO Br. at 26, 46), the fact remains that Trutek did not properly disclose the commissions-based reasonable royalty theory during discovery, summary

judgment, or in its motion for reconsideration.¹⁷ Trutek raises no argument that would justify reversing the district court's rulings, and the district court's judgment of no damages should be affirmed. "Evidence that was not before the district court at the time of the summary judgment proceeding . . . cannot be invoked to challenge the summary judgment order." *L & W*, 471 F.3d at 1315 n.2 (citing *Monarch Knitting*, 139 F.3d at 880; *Laitram*, 919 F.2d at 1581 & n.4).

2. The District Court Correctly Determined The Summary Judgment Record Supported Zero Damages

In the litigation below, the district court gave careful consideration to Trutek's repeated failure to disclose its damages case during fact and expert discovery, eventually ruling that on the record before it at summary judgment, the evidence supported an award of zero damages. Appx0052; Appx0058. Trutek offers no serious challenge to this ruling, other than to claim that the ruling was made in error in view of evidence and arguments that Trutek waived below. *See supra* Section II.B.1.

The only damages-related discovery produced by either party below was BlueWillow's sales document. Appx0043. Importantly, the sales document was never entered into the district court record on summary judgment (or at any other

¹⁷ Although Trutek states that the theory was raised in its motion for reconsideration (CO Br. at 26), it was not raised until later when briefing the issue of mootness. Appx0088.

later point in time). Due to the sensitive nature of the information, BlueWillow produced the sales document as Attorney's Eyes Only.¹⁸ Just as BlueWillow did, Trutek could have availed itself of the procedure for filing material under seal in the district court but it did not do so. *See, e.g.*, Appx00873-79; Appx0982-97. Instead, in its opposition to BlueWillow's motion for summary judgment, Trutek merely described the document as containing "most of the information requested in Plaintiff's Interrogatory No. 11", which sought: "(a) the entities to which [NanoBio® Protect] was sold; (b) the monetary amount of sales to each entity; (c) the total sales for [NanoBio® Protect]; (d) the unit price of [NanoBio® Protect] sold to each entity; and (e) the cost of each unit sold to each entity."¹⁹ Appx0947-49; *see also* Appx0047 ("Trutek does not describe the information in the sales document except to represent that it demonstrates the number of sales, the amount of sales, and the customers to whom the sales were made.").

Faced with only attorney argument generally describing the purported contents of the sales document, the district court properly concluded that while the sales document may relate to the royalty base, any analysis under the *Georgia-*

¹⁸ Court have recognized a party has an interest in preventing the disclosure of sensitive commercial information. *See United States v. Serta Assoc., Inc.*, 29 F.R.D. 136, 138 (N.D. Ill. 1961); *Mannington Mills, Inc. v. Armstrong World Indus., Inc.*, 206 F.R.D. 525, 529-32 (D. Del. 2002); *Cytodyne Techs., Inc. v. Biogenic Techs., Inc.*, 216 F.R.D. 533, 535 (M.D. Fla. 2003).

¹⁹ As described in its Response to Trutek's Motion to supplement the record, BlueWillow opposes adding the sales document to the record on appeal. BW Resp.

Pacific factors as to the appropriate royalty rate would be entirely speculative. Appx0050. This was the correct result. In *Info-Hold*, while the district court struck plaintiff's expert's report and precluded him from testifying, plaintiff could still rely on defendant's expert analysis of a reasonable royalty, a prior license for the patent, the royalty rate for the patent assignment, the profitability of the accused system, and more. *See* 783 F.3d at 1369, 1372. Trutek cannot point to any of that information, despite most of it being in its control.

On appeal, Trutek attempts to shift the blame to BlueWillow for its own failure to disclose its damages theories and properly support its arguments on summary judgment with record evidence. For example, Trutek criticizes BlueWillow for not seeking Trutek's damages theory via fact deposition. CO Br. at 52. But it is not BlueWillow's burden to disclose Trutek's damages theory, it is Trutek's. Trutek's argument is also nonsensical. If Trutek's fact witnesses were aware of the reasonable royalty theory it relies on now, back during the fact discovery phase, there is no excuse for Trutek's failure to disclose the theory until after the conclusion of summary judgment.

Trutek also argues that the district court's characterization of the sales document on summary judgment was made in error based on the wholly inaccurate and unsupported assertion that "BlueWillow's counsel, Liane Peterson, will not permit this document to be uploaded either to the District Court or to the Federal

Circuit, even UNDER SEAL.” CO Br. at 42. Trutek points to no evidence to support the assertion that BlueWillow’s counsel refused to permit the document to be filed under seal at the district court, and BlueWillow’s counsel made no such refusal. Indeed, there is no reason why Trutek could not have filed the document under seal at the district court. The local rules permit motions to file under seal and BlueWillow availed itself of this procedure. Appx00873-79; Appx0982-97; E.D. Mich. LR 5.3(b)(2). At the appeal stage, BlueWillow notified Trutek of its objection to Trutek’s proposed inclusion of the sales document in the Appendix because it was not part of the district court record and, thus, not appropriate for inclusion in the Appendix. *See* Fed. R. App. P. 10(a). Separate and apart from that objection, due to the highly confidential nature of the sales document, BlueWillow also objects to its inclusion on the public record.

Although Trutek argues the district court’s rulings are “unfair and unjust,” Trutek has no one to blame but itself. The district court correctly concluded based on the summary judgment record that Trutek could not meet its burden of proving the amount of a reasonable royalty. Appx0050. This Court should affirm summary judgment of no damages.

3. Trutek Remains Precluded from Proving the Amount of Any Damages at Trial

Regardless of Trutek’s appeal of the decision of no damages, the district court’s motion *in limine* decision “precludes Trutek from relying on undisclosed

damages evidence, including unidentified testimony from unidentified damages witnesses, in support of undisclosed damages theories.” Appx0035. There can be no dispute that Trutek’s commissions-based reasonable royalty theory is subject to exclusion under the district court’s order. The theory was not disclosed until after summary judgment and thus, necessarily must have been undisclosed as of the date of the district court’s exclusion order.

In issuing the *in limine* decision, the court acknowledged that, “[g]iven the extent of non-disclosure, the court’s exclusion effectively precludes Trutek from seeking damages. Assuming Trutek suffered damages remediable by a damages award, the reality is that Trutek never adequately asserted a claim for damages.” *Id.* The court further noted that “although Trutek notified BlueWillow that it seeks lost profits, Trutek has not disclosed either a claimed profit margin to be applied to Trutek’s lost sales or supporting damages evidence in its own possession” and “Trutek has not disclosed either a claimed royalty rate to be applied to BlueWillow’s sales or supporting damages evidence in its own possession.”

Appx0035-36.

On appeal, Trutek appears to mistakenly view the court’s motion *in limine* order to only preclude introduction of lost profits theories and evidence. CO Br. at 24, 44. The court’s decision, however, precludes Trutek from introducing undisclosed evidence related to both lost profits and a reasonable royalty at trial,

and any previously undisclosed theories such as the commissions-based reasonable royalty theory. Appx0035-36. “Although the court’s exclusion effectively precludes Trutek from seeking damages, this is only because that which Trutek seeks to present and that which Trutek has not disclosed pursuant to its discovery obligations are one and the same.” Appx0036. The district court’s grant of summary judgment should be affirmed for this additional reason.

III. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION IN DISMISSING TRUTEK’S COMPLAINT WITH PREJUDICE

Article III of the Constitution grants the courts the ability to adjudicate cases and controversies arising under the laws of the United States. U.S. CONST. art. III, § 2; *Nat'l Rifle Assoc. of Am. v. Magaw*, 132 F.3d 272, 279 (6th Cir. 1997). A case is no longer a controversy, and becomes moot, “when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome,” namely, the injury is no longer redressable. *Murphy v. Hunt*, 455 U.S. 478, 481 (1982) (citations omitted); *see also Already, LLC v. Nike, Inc.*, 568 U.S. 85, 90-91 (2013); *Cleveland Branch, N.A.A.C.P. v. City of Parma, OH*, 263 F.3d 513, 530-31 (6th Cir. 2001).

While a defendant’s voluntary cessation of the alleged wrongful behavior does not automatically deprive a court of the ability to hear the case, “[a] case might become moot if subsequent events [make] it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.” *Friends of*

the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc., 528 U.S. 167, 189 (2000) (citations omitted). For instance, a case might be moot when a party issues a covenant not to engage in the wrongful behavior, *see Already*, 568 U.S. at 100, or disavows any appeal of an unfavorable decision, *see ABS Global, Inc. v. Cytonome/ST, LLC*, 984 F.3d 1017, 1022-23 (Fed. Cir. 2021). “The decision to grant or deny permanent injunctive relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion.” *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006).

Once the district court granted BlueWillow’s summary judgment motion of no damages, the only remaining form of relief to which Trutek pled was injunctive relief. Appx0116-17. The district court explained that BlueWillow presented a reasoned argument on summary judgment for why no injunction should issue, but that Trutek failed to respond. Appx0058; Appx0090. When given a second chance, Trutek attempted to justify the need for injunctive relief by broadening the scope to other, non-litigated products such as the developmental vaccines. The district court correctly rejected this argument, noting that the scope of relief cannot extend beyond issues actually litigated. Appx0093 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 915 F.2d 670, 675 (Fed. Cir. 1990) and *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 911 (Fed. Cir. 2014)).

Trutek does not dispute that the only accused product, NanoBio® Protect, is no longer sold and has not been sold since shortly after the case was filed. Appx0195; Appx0205. In support of its withdrawal from the market, BlueWillow filed with the district court a declaration from its President and Chief Executive Officer, Chad Costley, swearing that “BlueWillow will not sell NanoBio® Protect at any time in the future.” Appx1083 at ¶ 8. The Costley declaration was signed under penalty of perjury, filed with the district court and thus, is part of the record. *Id.* at ¶ 9.

The district court considered the Costley declaration to function similar to a covenant that BlueWillow will not make, use, sell, offer to sell, or import NanoBio® Protect until after expiration of the ’802 patent. Appx0090. Because the “covenant” is coextensive with Trutek’s claim for infringement, the district court properly found BlueWillow had satisfied the voluntary cessation doctrine, and Trutek’s remaining claim for relief was moot. *Id.*

On appeal, Trutek raises two arguments that were considered and rejected by the district court. First, Trutek asserts that “BlueWillow is currently working to commercialize the same electrostatic technology that is recited in the claims of the ’802 patent.” CO Br. at 27. Yet Trutek acknowledges this commercialization effort is directed to BlueWillow’s vaccine development, “a technology that is protected by the safe harbor of 35 U.S.C. § 271(e)(1).” *Id.* Indeed, the district court

repeatedly rejected Trutek’s attempt to add allegations of infringement directed to the developmental vaccines to the case below. Appx0091 (“BlueWillow’s developmental vaccine candidates are not, and cannot be, part of this case because they ‘are protected under the safe harbor provision of 35 U.S.C. § 271(e)(1).’”)(citing Appx0426). The district court also correctly determined that the scope of any injunctive relief in the underlying litigation could not extend to the developmental vaccines both because of the safe harbor and the fact that any such infringement would not have been litigated in the case. Appx0093-95.

To the extent Trutek’s argument on appeal is similarly premised on some other, unidentified activity of BlueWillow, it would be improper to extend any injunctive relief to that activity for the same reasons already articulated by the district court. For example, Trutek refers to the possibility of BlueWillow “selling a product with similar technology” and makes the unsupported assertion that “BlueWillow is currently developing and refining its adjuvant technology that is possibly independent of their vaccine development.” CO Br. at 46-47, 47 fn. 6. Trutek does not cite any evidence in support of its assertion, let alone explain how the “refinement” might render the technology different from that which has been litigated in the current case. Trutek’s argument is nothing other than a repackaged version of the same argument already presented to and rejected by the district court. Appx0092-95.

Second, Trutek asserts that the Costley declaration is insufficient as BlueWillow could simply reintroduce NanoBio® Protect under another name. CO Br. at 61-62. Trutek offers no evidence to suggest BlueWillow is considering resuming sales, indeed, no such evidence exists. Moreover, the FDA warning letter issued with respect to NanoBio® Protect demonstrates that it is unlikely that the product would be reintroduced, even under a different name, as that would raise the same outstanding FDA issues. *See Appx0548; Appx0609-14; see also Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1382, 1391 (Fed. Cir. 2014) (finding FDA regulatory requirements relevant to voluntary cessation doctrine and issue of whether the allegedly infringing conduct is reasonably expected to recur).

While Trutek might not agree with the district court's decision, it does not present any evidence that the decision was manifestly erroneous or that the district court abused its discretion.²⁰ The dismissal with prejudice should be affirmed.

²⁰ To the extent Trutek takes issue with the fact that its complaint was dismissed with prejudice, while BlueWillow's counterclaim of patent invalidity was dismissed without prejudice, “[u]nder Sixth Circuit law, the decision whether to dismiss with or without prejudice is committed to the sound discretion of the district court.” *H.R. Tech., Inc. v. Astechnologies, Inc.*, 275 F.3d 1378, 1384 (Fed. Cir. 2002).

IV. CONCLUSION

For the foregoing reasons, BlueWillow asks this Court to affirm the district court's grant of summary judgment of no pre-suit damages, affirm the district court's grant of summary judgment of no damages, and affirm the district court's dismissal of the case with prejudice.

Dated: July 22, 2024

/s/ Liane Peterson

FOLEY & LARDNER LLP

Liane Peterson

Bradley Roush

Washington Harbour

3000 K Street, N.W.

Suite 600

Washington, DC 20007-5101

Telephone: 202.672.5300

Facsimile: 202.672.5399

Attorneys for Appellee BlueWillow Biologics, Inc.

CERTIFICATE OF SERVICE

I certify that on July 22, 2024, I served the foregoing document upon all parties/counsel of record, by filing a copy of same using the Court's CM/ECF System. I also sent said foregoing document to all parties/counsel of record via email.

/s/ Liane M. Peterson
Liane M. Peterson
Attorney for Appellee

FORM 19. Certificate of Compliance with Type-Volume Limitations

Form 19
July 2020UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS****Case Number:** 24-1555**Short Case Caption:** Trutek Corp. v. BlueWillow Biologics, Inc.

Instructions: When computing a word, line, or page count, you may exclude any items listed as exempted under Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2).

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

- the filing has been prepared using a proportionally-spaced typeface and includes 11,924 words.
- the filing has been prepared using a monospaced typeface and includes _____ lines of text.
- the filing contains _____ pages / _____ words / _____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____).

Date: 07/22/2024Signature: /s/ Liane PetersonName: Liane Peterson